K131729

JUL 3 1 2013

10 510(k) Summary

510(k) Summary
BioFire Diagnostics, Inc.

Modification of the JBAIDS Plague Detection Kit for use with the IT *1-2-3*™ Platinum Path Sample Purification Kit Accessory

Introduction: According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitted by:

BioFire Diagnostics, Inc.
390 Wakara Way
Salt Lake City, UT 84108

Telephone: 801-736-6354
Facsimile: 801-588-0507

Contact: Cynthia Phillips, ext. 370

Date Submitted: June 10, 2013

Device Name and Classification:

Trade Name: JBAIDS Plague Detection Kit

Regulation Number: 21 CFR 866.3945

Classification Name: Reagent Kit: *Y. pestis*, Class II

Product Code: OIH

Predicate Device:

JBAIDS Plague Detection Kit (K072613)

Intended Use:

The Joint Biological Agent Identification and Diagnostic System (JBAIDS) Plague Detection Kit is a real-time polymerase chain reaction (PCR) test kit intended for the qualitative *in vitro* diagnostic (IVD) detection of target DNA sequences of *Yersinia pestis*. The kit can be used to test human whole blood collected in sodium citrate or

sputum collected aseptically from individuals greater than 18 years of age suspected of having septic or pneumonic plague. In addition, positive blood cultures and colonies may be tested. The JBAIDS Plague Target 2 assay is used as a supplementary test only after a positive result with the Target 1 Assay.

The JBAIDS Plague Target 1 and Target 2 assays are run on the JBAIDS instrument using the Diagnostic Wizard. Results are for the presumptive identification of *Y. pestis* in conjunction with culture and other laboratory tests. The definitive identification of *Y. pestis* from colony growth, liquid blood culture growth, or from blood or sputum specimens requires additional testing and confirmation procedures in consultation with public health or other authorities for whom reports are required.

The diagnosis of plague must be made based on history, signs, symptoms, exposure likelihood, and other laboratory evidence in addition to the identification of *Y. pestis* from cultures or directly from whole blood or sputum specimens.

The JBAIDS Plague Detection Kit is intended for use by trained clinical laboratory personnel who have received specific training on the use of the JBAIDS Plague Detection Kit. The level of *Y. pestis* that would be present in blood or sputum from individuals with early systemic infection is unknown. Due to the difficulty in obtaining clinical specimens, these assays were not evaluated with blood or sputum from individuals with septic or pneumonic plague.

Device Description:

The Joint Biological Agent Identification and Diagnostic System (JBAIDS) Plague Detection System is a fully integrated IVD system composed of the portable JBAIDS instrument, laptop computer and software and the JBAIDS Plague Detection Kit with two different freeze-dried PCR assays for detection of *Yersinia pestis* DNA. The system has been validated using four different sample preparation kits for isolating DNA from whole blood (IT *1-2-3*™ Platinum Path and QFLOW^{dna} Sample Purification Kits), sputum (IT *1-2-3*™ Platinum Path and IT *1-2-3*™ VIBE), positive blood cultures (IT *1-2-3*™ SWIPE Sample Purification Kit), and plate cultures (IT *1-2-3*™ Platinum Path and SWIPE Sample Purification Kits). Use of the JBAIDS DNA Extraction Control Kit is also recommended.

Prior to testing, specimens are processed using BioFire Diagnostic's IT *1-2-3* Sample Purification Kits. The resulting purified sample is added to Target 1 Unknown and Target 1 Inhibition Control vials, along with reconstitution buffer. Target 1 Positive Control and Negative Control vials are prepared using reconstitution buffer and water. When *Y. pestis* DNA is present, a fragment of *Y. pestis* DNA is amplified. The amplicon is detected by fluorescence using a specific hydrolysis probe. Each probe is labeled on one end with a fluorescent reporter moiety (6-carboxyfluorescein (6-FAM)) and elsewhere with a quencher moiety (carboxy tetramethylrhodamine (TAMRA)). When the probe is intact, the quencher absorbs the light emitted by the reporter moiety. During PCR, the probe hybridizes to the target sequence before the exonuclease activity of Taq polymerase hydrolyzes the probe, separating the fluorophore from the quencher and permitting

detection of the fluorescent signal generated by the reporter. The fluorescent signal increases as additional templates are amplified and more probes are hydrolyzed.

JBAIDS Software analyzes the fluorescence amplification curves and reports results as positive, negative, uncertain or inhibited. A failure of the Positive or Negative Control will result in the entire run being called invalid. Retesting is required to resolve uncertain, invalid or inhibited results. The Target 2 assay is used as a supplementary test only after a positive result is obtained with the Target 1 assay.

Substantial Equivalence:

The JBAIDS Plague Detection Kit is substantially equivalent to the previously cleared JBAIDS Plague Detection Kit. The following tables compare the modified JBAIDS Plague Detection Kit to the previously cleared JBAIDS Plague Detection Kits (K072613). The first table outlines the similarities between the two systems and the second table outlines the differences.

Table 1. Similarities between the New Device and the Predicate

Element	New Device: JBAIDS Plague Detection Kit	Predicate: JBAIDS Plague Detection Kit (K072613)
Intended Use	Identification of Plague infection through the detection of two DNA sequence targets unique to *Yersinia pestis*. Results are used in conjunction with clinical information, culture, and other laboratory tests as an aid in the diagnosis of systemic Plague infection in individuals suspected of having the disease.	Same
Technology	Real-time PCR using hydrolysis probes	Same
Organism Detected	Qualitative *in vitro* detection of *Yersinia pestis* DNA	Same
Specimen Types	Whole blood (collected in 3.2% sodium citrate), sputum collected aseptically from individuals greater than 18 years of age suspected of having septic or pneumonic plague, blood culture (grown in soybean-casein digest broth) or bacterial culture (grown on blood agar)	Same
Platform	JBAIDS Instrument	Same
Time Required for Analysis of Specimen	Less than 3 hours	Same

Table 2. Differences between the New Device and the Predicate

Element	New Device: JBAIDS Plague Detection Kit	Predicate: JBAIDS Plague Detection Kit (K072613)
DNA Extraction Methods	Whole blood purified with IT *1-2-3*™ Platinum Path or IT *1-2-3*™ QFLOW^{dna} Sample Purification Kits (or validated equivalent).	Whole blood purified with IT *1-2-3*™ QFLOW^{dna} Sample Purification Kit (or validated equivalent).
	Sputum purified with IT *1-2-3*™ Platinum Path or IT *1-2-3*™ VIBE Sample Purification Kits (or validated equivalent).	Sputum purified with IT *1-2-3*™ VIBE Sample Purification Kits (or validated equivalent).
	Blood culture purified with IT *1-2-3*™ SWIPE Sample Purification Kit (or validated equivalent).	Same
	Direct bacterial culture purified with IT *1-2-3*™ Platinum Path or IT *1-2-3*™ SWIPE Sample Purification Kit (or validated equivalent).	Direct bacterial culture purified with IT *1-2-3*™ SWIPE Sample Purification Kit (or validated equivalent).

Summary of Performance Data

Clinical Performance

True clinical specimens from patients infected with *Yersinia pestis* (plague), are not available for testing due to the extreme rarity of natural infection with these organisms. Therefore, two clinical evaluations using surrogate specimens were performed to validate the use of the IT *1-2-3*™ Platinum Path Sample Purification Kit for use with the JBAIDS Plague Detection Kit. For the evaluation using blood samples, whole blood specimens were prospectively collected from patients with fever, after which the samples were spiked with inactivated *Y. pestis*, purified by both the new and old extraction methods, and then tested. For the evaluation using sputum samples, residual frozen sputum specimens were spiked with inactivated *Y. pestis*, purified by both the new and old extraction methods, and then tested.

Testing of Surrogate Whole Blood Clinical Specimens

One hundred (100) surrogate whole blood samples were prepared using prospectively collected specimens that were collected from febrile volunteers from November of 2012 into April of 2013. Fifty (50) of the specimens were spiked with inactivated *Y. pestis* at concentrations near and above the system LoD, while the remaining 50 specimens were not spiked with *Y. pestis*. Samples were then processed using both the new nucleic acid extraction method (Platinum Path) and the original nucleic acid extraction method (IT *1-2-3*™ QFLOW^{dna} Sample Purification Kit; QFLOW^{dna}) followed by testing with the JBAIDS Plague Detection Kit. JBAIDS operators were blinded to the analyte content of the samples. Table 3 presents the Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) for the surrogate whole blood specimen testing. In this study,

a success was defined as a surrogate sample having identical JBAIDS results for both the Platinum Path and QFLOW^{dna} processed samples, where the JBAIDS result for a sample purified using from the QFLOW^{dna} kit was considered the correct result. Overall percent agreement between the two purification kits was 99% with a lower bound of the 95% confidence interval at 94%. The IT *1-2-3* QFLOW^{dna} and Platinum Path Sample Purification Kits performed equivalently with respect to detection of *Y. pestis* in surrogate whole blood specimens tested with the JBAIDS Plague Detection Kit.

Table 3. JBAIDS Plague Detection Kit Performance on Spiked Whole Blood Samples Processed with the IT *1-2-3* Platinum Path and QFLOW^{dna} Sample Purification Kits

Positive Agreement				Negative Agreement			
QFLOW^{dna} + Platinum Path +	QFLOW^{dna} + Platinum Path -	PPA	95% CI[a]	QFLOW^{dna} - Platinum Path -	QFLOW^{dna} - Platinum Path +	NPA	95% CI
49	0	100% (49/49)	92.7-100%	50	1[b]	98% (50/51)	89.6-99.9%

[a] C.J. Clopper and E.S. Pearson. 1934. The use of confidence or fiducial limits illustrated in the case of the binomial. Biometrika 26:404-413.

[b] One false positive result was obtained for a specimen spiked at the 1×LoD level for which the result was positive for the Platinum Path purified sample, but negative for the QFLOW^{dna} purified sample. When a sample is spiked at the 1×LoD level, ≥ 95% of results are expected to be positive. Occasional negative results are therefore expected (approximately 1 out of 20), with the consequence in this case of a false positive comparative result for a specimen spiked at the 1×LoD level.

Testing of Surrogate Sputum Clinical Specimens

One hundred (100) surrogate sputum samples were prepared using frozen residual sputum specimens. Fifty (50) of the samples were spiked with inactivated *Y. pestis* at concentrations near and above the system LoD, while the remaining 50 specimens were not spiked with *Y. pestis*. Samples were then processed using both the new nucleic acid extraction method (Platinum Path) and the original nucleic acid extraction method (IT *1-2-3*™ VIBE Sample Purification Kit) followed by testing with the JBAIDS Plague Detection Kit. JBAIDS operators were blinded to the analyte content of the samples. Table 4 presents the PPA and NPA for the surrogate sputum clinical specimen testing. Overall percent agreement between the two purification kits was 99% (99/100; 95% CI = 94.6-100%). The IT *1-2-3* VIBE and Platinum Path Sample Purification Kits performed equivalently with respect to detection of *Y. pestis* in surrogate sputum samples tested with the JBAIDS Plague Detection Kit.

Table 4. JBAIDS Plague Detection Kit Performance on Spiked Sputum Samples Processed with the IT *1-2-3* Platinum Path and VIBE Sample Purification Kits

Positive Agreement				Negative Agreement			
VIBE + Plat Path +	VIBE + Plat Path -	PPA	95% CI[a]	VIBE - Plat Path -	VIBE - Plat Path +	NPA	95% CI[a]
50	0	100% (50/50)	92.9-100%	49	1[b]	98% (49/50)	89.4–100%

[a] C.J. Clopper and E.S. Pearson. 1934. The use of confidence or fiducial limits illustrated in the case of the binomial. Biometrika 26:404-413.

[b] A single Platinum Path-purified sputum sample not spiked with *Y. pestis* gave a false positive result. It may have been contaminated with *Y. pestis* during processing or testing, as PCR amplification of that sample was delayed relative to samples spiked at the 1×LoD level, and no other false positive results were obtained during the study.

Selected Analytic Studies

Limit of Detection

Twenty out of 20 independent whole blood specimens spiked with *Y. pestis* at the previously established LoD level and processed with the IT *1-2-3* Platinum Path Sample Purification Kit were detected with the JBAIDS Plague Detection Kit. This confirmed the LoD of 50 CFU/mL in whole blood that was previously established for whole blood samples processed using the IT *1-2-3* QFLOW^{dna} Sample Purification Kit.

Twenty out of 20 independent sputum specimens spiked with *Y. pestis* at the LoD level and processed with the IT *1-2-3* Platinum Path Sample Purification Kit were detected with the JBAIDS Plague Detection Kit. This confirmed the LoD of 670 CFU/mL in sputum previously established for sputum samples processed using the IT *1-2-3* VIBE Sample Purification Kit.

Table 5. Confirmation of the *Y. pestis* LoDs for Platinum Path-Purified Whole Blood and Sputum Samples Tested with the JBAIDS Plague Detection Kit

Sample Matrix	Spiked *Y. pestis* Concentration (CFU/mL)	Plague Assay	# Positive	% Positive	Plague Target Assay Mean Cp +/- Std Dev
Whole Blood	50	Target 1	20/20	100.0%	34.25 ± 1.18
		Target 2	19/20	95.0%	34.67 ± 1.01
Sputum	670	Target 1	20/20	100.0%	31.17 ± 0.93
		Target 2	20/20	100.0%	31.91 ± 1.68

Reproducibility

A multicenter study was performed to determine the overall system reproducibility when whole blood and sputum samples were processed with the IT *1-2-3* Platinum Path Sample Purification Kit prior to testing with the JBAIDS Plague Detection Kit.

A panel of 12 blood samples was tested twice each day for four days at each of three testing sites. The panel contained four samples spiked with inactivated *Y. pestis* CO92 strain at a medium positive (5×LoD) level, four samples spiked at a low positive level

(1×LoD), and four samples that were not spiked. Results for whole blood testing are summarized in Table 6.

A panel of nine sputum samples was similarly tested twice each day for five days at each of three testing sites. This panel contained three samples spiked with inactivated *Y. pestis* CO92 strain at a medium positive (5×LoD) level, three samples spiked at a low positive level (1×LoD), and three samples that were not spiked. Results for sputum testing are summarized in Table 7. The detection rate was >99% for both whole blood and sputum samples containing *Y. pestis* spiked near or above the LoD for the respective sample matrix. True negative whole blood and sputum samples did not have 100% negative results for each individual target assay, but since both targets must be detected for a final positive result for Plague, there were no final false positive results for unspiked samples. The JBAIDS Plague Detection System is reproducible when used to test whole blood and sputum samples processed with the IT *1-2-3* Platinum Path Sample Purification Kit.

Table 6. Reproducibility of the Plague Target 1 and Target 2 Assays in the JBAIDS Plague Detection Kit for Whole Blood Samples Purified with the IT *1-2-3* Platinum Path Purification Kit

Blood Spike Level	Test Location	Plague Target 1							Plague Target 2						
		Number Positive	Number Negative	% Agreement with Expected Result	95% CI	Mean Cp	Std Dev	%CV	Number Positive	Number Negative	% Agreement with Expected Result	95% CI	Mean Cp	Std Dev	%CV
Medium Positive (5xLoD)	Site 1	32/32	0/32	100%		29.66	0.95	3.20	32/32	0/32	100%		32.52	0.86	2.64
	Site 2	32/32	0/32	100%		28.75	0.87	3.03	32/32	0/32	100%		31.80	0.83	2.61
	Site 3	32/32	0/32	100%		28.51	1.40	4.91	32/32	0/32	100%		31.04	0.93	3.00
	All Sites	**96/96**	**0/96**	**100%**	**96.2-100**	**28.98**	**1.20**	**4.14**	**96/96**	**0/96**	**100%**	**96.2-100**	**31.79**	**1.06**	**3.33**
Low Positive (1xLoD)	Site 1	32/32	0/32	100%		31.16	0.98	3.15	31/32[a]	0/32	96.9%		33.88	1.16	3.42
	Site 2	32/32	0/32	100%		30.08	1.27	4.22	32/32	0/32	100%		32.67	1.01	3.09
	Site 3	32/32	0/32	100%		29.55	0.96	3.25	32/32	0/32	100%		32.09	0.65	2.03
	All Sites	**96/96**	**0/96**	**100%**	**96.2-100**	**30.26**	**1.27**	**4.20**	**95/96**	**0/96**	**98.9%**	**94.3-99.9**	**32.88**	**1.21**	**3.68**
Negative	Site 1	0/32	32/32	100%					1/32	31/32	96.9%		36.40[d]		
	Site 2	0/32	31/32[b]	96.9%					0/32	31/32[c]	96.9%				
	Site 3	0/32	32/32	100%					0/32	32/32	100%				
	All Sites	**0/96**	**95/96**	**98.9%**	**94.3-99.9**				**1/96**	**94/96**	**97.9%**	**92.7-99.7**	**36.40[d]**		

[a] One initial Uncertain result; retest also Uncertain.
[b] One initial Inhibited result; retest Inhibited for undiluted sample and negative for 1:10 dilution; no further testing.
[c] One initial Inhibited result; inadequate volume for retesting.
[d] Mean Cp for single false positive sample

Table 7. Reproducibility of the Plague Target 1 and Target 2 Assays in the JBAIDS Plague Detection Kit for Sputum Samples Purified with the IT *1-2-3* Platinum Path Purification Kit

Sputum Spike Level	Test Location	Plague Target 1							Plague Target 2						
		Number Positive	Number Negative	% Agreement with Expected Result	95% CI	Mean Cp	Std Dev	%CV	Number Positive	Number Negative	% Agreement with Expected Result	95% CI	Mean Cp	Std Dev	%CV
Medium Positive (5xLoD)	Site 1	29/30	1/30	96.7%		29.82	0.70	2.35	30/30	0/30	100%		32.70	0.70	2.14
	Site 2	30/30	0/30	100%		28.60	0.59	1.88	30/30	0/30	100%		31.61	0.57	1.80
	Site 3	30/30	0/30	100%		27.59	0.58	2.10	30/30	0/30	100%		30.80	0.53	1.72
	All Sites	**89/90**	**1/90**	**98.9%**	**94.0-99.9**	**28.65**	**1.10**	**3.84**	**90/90**	**0/90**	**100%**	**96.0-100**	**31.70**	**0.99**	**3.12**
Low Positive (1xLoD)	Site 1	30/30	0/30	100%		32.60	0.77	2.36	30/30	0/30	100%		35.62	1.19	3.34
	Site 2	30/30	0/30	100%		31.31	0.58	2.03	30/30	0/30	100%		34.40	0.59	1.72
	Site 3	30/30	0/30	100%		30.36	0.67	2.21	30/30	0/30	100%		33.48	0.72	2.15
	All Sites	**90/90**	**0/90**	**100%**	**96.0-100**	**31.42**	**1.14**	**3.63**	**90/90**	**0/90**	**100%**	**96.0-100**	**34.50**	**1.23**	**3.57**
Negative	Site 1	0/30	30/30	100%					0/30	30/30	100%				
	Site 2	0/30	29/30[a]	96.7%					0/30	30/30	100%				
	Site 3	0/30	30/30	100%					0/30	30/30	100%				
	All Sites	**0/90**	**89/90**	**98.9%**	**94.0-99.9**				**0/90**	**90/90**	**100%**	**96.0-100**			

[a] One initial Uncertain result; retest also Uncertain.

Detection of Direct Culture Samples Processed with the IT 1-2-3 Platinum Path Sample Purification Kit

Y. pestis colonies can be detected using a modified Platinum Path protocol to process the colonies followed by testing with the JBAIDS Plague Detection Kit. Ten *Yersinia pestis* colonies were purified alongside ten non- *Y. pestis* colonies. All ten *Y. pestis* colonies were detected with the JBAIDS Plague Detection Kit, while the non- *Y. pestis* colonies were not detected.

Table 8. Plague Target 1 and Target 2 Detection from Colonies Purified with Platinum Path

Colony Type	Plague Target 1			Plague Target 2		
	Positive Results/Total	Cp (cycles)		Positive Results/Total	Cp (cycles)	
		Mean	SD		Mean	SD
Y. pestis	**10/10**	19.25	0.74	**10/10**	20.70	0.67
Non- Y. pestis	**0/10**	-	-	**0/10**	-	-

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

CYNTHIA PHILLIPS, Ph.D.
MANAGER, JBAIDS REGULATED PRODUCTS
BIOFIRE DIAGNOSTICS, INC.
390 WAKARA WAY
SALT LAKE CITY UT 84108

July 31, 2013

Re: K131729
Trade/Device Name: JBAIDS Plague Detection Kit
Regulation Number: 21 CFR 866.3945
Regulation Name: In vitro diagnostic device for Yersinia spp. detection
Regulatory Class: II
Product Code: OIH
Dated: June 10, 2013
Received: June 12, 2013

Dear Dr. Phillips:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Uwe Scherf -S for

Sally A. Hojvat, M.Sc., Ph.D.
Director, Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K131729
Device Name: JBAIDS Plague Detection System

The Joint Biological Agent Identification and Diagnostic System (JBAIDS) Plague Detection Kit is a real-time polymerase chain reaction (PCR) test kit intended for the qualitative *in vitro* diagnostic (IVD) detection of target DNA sequences of *Yersinia pestis*. The kit can be used to test human whole blood collected in sodium citrate or sputum collected aseptically from individuals greater than 18 years of age suspected of having septic or pneumonic plague. In addition, positive blood cultures and colonies may be tested. The JBAIDS Plague Target 2 assay is used as a supplementary test only after a positive result with the Target 1 Assay.

The JBAIDS Plague Target 1 and Target 2 assays are run on the JBAIDS instrument using the Diagnostic Wizard. Results are for the presumptive identification of *Y. pestis* in conjunction with culture and other laboratory tests. The definitive identification of *Y. pestis* from colony growth, liquid blood culture growth, or from blood or sputum specimens requires additional testing and confirmation procedures in consultation with public health or other authorities for whom reports are required.

The diagnosis of plague must be made based on history, signs, symptoms, exposure likelihood, and other laboratory evidence in addition to the identification of *Y. pestis* from cultures or directly from whole blood or sputum specimens.

The JBAIDS Plague Detection Kit is intended for use by trained clinical laboratory personnel who have received specific training on the use of the JBAIDS Plague Detection Kit. The level of *Y. pestis* that would be present in blood or sputum from individuals with early systemic infection is unknown. Due to the difficulty in obtaining clinical specimens, these assays were not evaluated with blood or sputum from individuals with septic or pneumonic plague.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

John Hobson -S
2013.07.31 10:04:30
-04'00'